REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the present amendment, new claims 41, 42 and 43 have been added. These claims are directed to "an immunogenic composition." Support for these claims appear on at least page 19, lines 19 to 23, of the specification as filed. Accordingly, applicants submit that no new matter has been added via this amendment.

Turning now to the Office Action, claims 36, 37 and 40 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. For the following reasons, this rejection is respectfully traversed.

In rendering this rejection, the Examiner has purported that the specification does not enable a vaccine composition for malaria since the specification purportedly only describes the construction of a genomic DNA library and immunological screening of the bank.

However, as set forth in the enclosed 1.132 Declaration of Pierre Druilhe ("the Declaration") other data is provided in the specification concerning the immunogenicity of the particular peptides in mice, in chimpanzees and in African adults previously infected with malaria.

Indeed, the specification discloses that a T epitope is recognized in about 825 subjects exposed to malaria and that this T epitope resides in the LSA-R-NR peptide. In more than 500 individuals exposed to malaria, this particular T epitope is

recognized in 95% of these individuals. Moreover, 65% of subjects exposed to malaria recognized the B epitope in the LSA-NR peptide.

Applicants submit that the recognition of these epitopes by subjects exposed to malaria is an indication that the peptide has vaccinating capabilities and therefore can be used in a vaccine composition.

Moreover, the Examiner has cited specific articles, which she has deemed to show "[t]he state of the art indicates that at present there are no vaccines that protect against malaria." The Examiner has further relied on the disclosure of 1999 in Shi et al. as teaching that only a multicomponent, multistage malaria vaccine can induce immune responses. However, applicants submit that these articles are not reflective of the current state of the art.

Indeed, the Examiner has provided articles from the years 1992 to 2001 and deemed that these documents reflect the state of the art. However, applicants submit that the state of the art is reflected in Document I attached to the Declaration, as well as the enclosed Document II. Both of these documents post-date the references supplied by the Examiner and indicate that LSA-1 antigens are in clinical trials and have been shown to provide protective immunity (Document I).

Furthermore, Documents I and II demonstrate that single-antigen based vaccines are feasible. Thus, the reliance by the Examiner on Shi et al. that only multistage vaccines could only be effective as vaccines is erroneous, as evidenced by Documents I and II.

Moreover, it appears that the Examiner's position is that a vaccine has to provide life-long total prophylaxis against infection. However, this standard is rarely achieved in a vaccine. In fact, most vaccines do not prevent infection and do not

provide life-long immunity. An example of such a vaccine is a tetanus toxoid vaccine that has to be administered many times during a person's lifetime, yet it is still considered a vaccine. The rabies vaccine is rarely administered prior to infection, but protects people from acquiring rabies after they have been infected. Thus, according to the Examiner's position, the rabies vaccine would not be considered to be a vaccine since the person has already been infected. Also, the polio vaccine when administered in some instances did not prevent but caused polio and yet it is still considered a vaccine.

Thus, the narrow and limited definition of the Examiner in maintaining this rejection falls out of the norm for one skilled in the vaccine art.

Also, in the Declaration, it is deemed by Professor Druilhe that most vaccines do not prevent against infection, but merely enhance the immune system to limit the pathogen. Therefore, the presence of T and B epitopes on the LSA-1 peptides of the present invention, as indicated by Professor Druilhe in the Declaration is a clear indication that these peptides have vaccinating capabilities.

Furthermore, it is well known in the art that there are various levels of effectiveness in various vaccines, but they are still referred to as vaccines. The category of 100% effectiveness is not a requirement for a composition to be called a vaccine.

Moreover, applicants are not aware of any legal requirement that a vaccine composition has to be approved in a clinical trial and on the market prior to being allowed in a claim in the United States Patent and Trademark Office. To the contrary, the Federal Circuit has previously admonished the United States Patent and Trademark Office for confusing the requirements for obtaining a patent with the

requirements for obtaining government approval to market a particular product for human consumption/administration. *See In re Brana*, 34 U.S.P.Q.2d 1437, 1442 (Fed. Cir. 1995).

Finally, applicants want to clarify a statement in the publication of Kurtis et al. (2001), which is relied upon by the Examiner. The statement in Kurtis et al. that since "LSA is a liver specific antigen, the investigation is restricted to human studies . . ." does not mean that the testing of liver stage antigens has to be done only in humans, since there are no animal models. Rather, this quote means that no animal models harbor the LSA-1 peptide. Immunogenicity of the LSA-1 peptides can be undertaken with Aotus monkeys as set forth in paragraph (9) of the Declaration by Professor Druilhe.

In conclusion, applicants submit that the present invention describing LSA-1 peptides having T and B epitopes, the confirmation of these epitopes on people which were subjected to malaria and among other scientific evidence set forth in the specification and the showing in clinical trials that LSA-1 peptides confer protective immunity can only lead to the conclusion that the specification is in fact enabled to a person skilled in the vaccine arts.

Therefore, in view of the above, withdrawal of this enablement rejection is respectfully requested.

Claims 31, 35, 36 and 39 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1-3 of U.S. Patent No. 6,319,502; and (ii) claims 1-6 of U.S. Patent No. 6,270,771. Both of these rejections are respectfully traversed. However, to expedite prosecution in the present application, and not to acquiesce to the Examiner's

rejections, applicants are submitting herewith Terminal Disclaimers which should obviate both of these rejections.

Finally, claims 31, 32, 35-37, 39 and 40 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 25 of co-pending Application No. 09/900,963. This rejection is also respectfully traversed.

Claims 1-26 of copending Application No. 09/900,963 were canceled in a Preliminary Amendment filed on July 10, 2001 with the originally-filed divisional application. Therefore, the Examiner's provisional rejection in the subject application over canceled claims in the copending application is improper (or at least moot).

Even if the Examiner considers the provisional rejection to be proper, section 804 of the M.P.E.P. states that:

> [i]f the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby concerting the "provisional" double patenting rejection in the other [application] into a double patenting rejection at the time the one application issues as a patent.

Therefore, should this provisional rejection be the only remaining rejection in the subject application, the Examiner should at least withdraw the rejection in accordance with the instructions set forth in the M.P.E.P.

In either scenario, withdrawal of this provisional obviousness-type double patenting rejection is respectfully requested.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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